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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/084,598      | 02/25/2002  | Howard Boilen        | A20-010             | 5748             |

7590                    06/04/2003

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[REDACTED] EXAMINER

OH, SIMON J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615     | 5            |

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                         |  |  |
|--|-------------------------|--|--|
| <b>Office Action Summary</b>   | Application No.         | Applicant(s)   |  |
|  | 10/084,598              | BOILEN ET AL.  |  |
|  | Examiner<br>Simon J. Oh | Art Unit<br>1615   |  |
| -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  |                         |  |  |
| <b>Period for Reply</b>  |                         |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                         |  |  |
| <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> |                         |  |  |
| <b>Status</b>  |                         |  |  |
| 1) <input type="checkbox"/> Responsive to communication(s) filed on _____.   |                         |  |  |
| 2a) <input type="checkbox"/> This action is <b>FINAL</b> .                    2b) <input checked="" type="checkbox"/> This action is non-final.  |                         |  |  |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                         |  |  |
| <b>Disposition of Claims</b>   |                         |  |  |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-33</u> is/are pending in the application.   |                         |  |  |
| 4a) Of the above claim(s) _____ is/are withdrawn from consideration.   |                         |  |  |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed.   |                         |  |  |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-33</u> is/are rejected.   |                         |  |  |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to.   |                         |  |  |
| 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.   |                         |  |  |
| <b>Application Papers</b>  |                         |  |  |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner.  |                         |  |  |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                         |  |  |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br>If approved, corrected drawings are required in reply to this Office action.  |                         |  |  |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.   |                         |  |  |
| <b>Priority under 35 U.S.C. §§ 119 and 120</b>   |                         |  |  |
| 13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).<br>a) <input type="checkbox"/> All    b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:<br>1. <input type="checkbox"/> Certified copies of the priority documents have been received.<br>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.<br>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).<br>* See the attached detailed Office action for a list of the certified copies not received.  |                         |  |  |
| 14) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).<br>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.   |                         |  |  |
| 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |                         |  |  |
| <b>Attachment(s)</b>   |                         |  |  |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  |                         | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   |                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .   |                         | 6) <input type="checkbox"/> Other: _____ .                                   |  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 32 is objected to because of the following informalities: The words “group” and “moisturizers” appear to be misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Riazi (U.S. Patent No. 5,674,268).

The Riazi patent discloses methods of a therapeutic heat treatment in which an extremity is dipped into a receptacle containing a melted wax composition. Once the wax composition on the extremity has cooled, it may then be peeled off (See Column 1, Lines 18-32). The disclosed invention is a method of such a therapeutic heat treatment comprising a shortened preparation time by use of microwave energy (See Column 1, Line 62 to Column 2, Line 37). The patent

also discloses microwave preparation methods of various preparation times at different microwave power settings (See Column 4, Lines 10-52). A thermometer is provided by which a subject can continue to heat the receptacle containing the preparation until a temperature of 130° F has been reached (See Column 4, Lines 53-61). The patent also discloses that while wax can be employed, wax compositions may also be used, in which the composition contains additional components that either aid in treatment or provide some benefit to the user (See Column 3, Lines 13-23).

Claims 20 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gardlik *et al.* (U.S. Patent Application Publication No. US 2002/0119174 A1)

The Gardlik *et al.* publication discloses a pharmaceutical composition, which may comprise up to about 99.999% by weight of a pharmaceutically acceptable vehicle. Such a vehicle comprises at least about 5% by weight of propylene glycol, and may also comprise water (See Section [0059]). The vehicle may also comprise a thickening agent, which may be typically present in an amount from about 0.05% to about 20% by weight. Such suitable thickening agents include cetyl alcohol and stearyl alcohol (See Sections [0061] and [0062]). The vehicle may also comprise emollients and humectants either alone or in combination with other vehicle ingredients, emollients, and humectants. Such emollients and humectants include waxes and hydrogenated vegetable oils. Waxes that are disclosed as being suitable in being all or part of the vehicle include paraffin wax (See Section [0089]). Hydrogenated castor oil is listed as being a suitable hydrogenated vegetable oil for use in the vehicle. Other useful emollients and

humectants include stearyl alcohol, cetyl alcohol, and glyceryl monostearate (See Sections [0075], and [0089] to [0092]). Optional components include surfactants, which may typically be included in an amount ranging from about 5% to about 50% by weight. Suitable anionic surfactants include alkyl sulfates and alkyl ether sulfates (See Sections [0095] to [0099]). Other optional components include activity enhancers, which may typically be employed in an amount ranging from about 0.001% to about 15% by weight. Vitamins are listed as one type of activity enhancer (See Sections [0282] and [0301]). The publication also discloses that the pH of the final product may be adjusted with any suitable pH adjuster (See Section [0035]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riazi in view of Gardlik *et al.*

The relevant portions of the Riazi patent are detailed in the above rejection of Claims 1, 15, 17, and 18 under 35 U.S.C. 102(b).

The Riazi patent does not teach specific quantities of components of a wax composition to be used in the disclosed treatment method.

The relevant portions of the Gardlik *et al.* publication are detailed in the above rejection of Claims 20 and 33 under 35 U.S.C. 102(e).

It would be obvious to one of ordinary skill in the art to combine the disclosures of the prior art into the objects of the instantly claimed invention.

The Riazi patent discloses that wax compositions comprising other therapeutic components may be used in place of wax in the disclosed invention. As paraffin wax compositions comprising therapeutic agents such as vitamins fall within the scope of the disclosure of the Gardlik *et al.* patent, it is the position of the examiner that one of ordinary skill in the art, would be motivated to use the paraffin compositions disclosed by Gardlik *et al.* in the invention of Riazi with a reasonable expectation of success. Although ranges of weight percentages of certain components of the compositions of Gardlik *et al.* are not explicitly disclosed therein, it is the position of the examiner that quantities of various percentages may themselves be adjusted by one of ordinary skill in the art to suit various purposes, absent a conclusive showing by the applicant of unexpected results by of one ordinary skill in the art.

Thus, the instantly claimed invention is *prima facie* obvious.

#### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo  
June 2, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600